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News Release

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Bayer to showcase new data from evolving Oncology portfolio at ESMO Virtual Congress 2020

- Long-term efficacy and safety results for larotrectinib (Vitrakvi™) from an integrated data set of adult and pediatric patients with TRK fusion cancer, as well as sub-analyses in advanced thyroid and lung cancer patients
- Tolerability and treatment response data from the Phase III ARAMIS trial investigating darolutamide (Nubeqa™) in men with non-metastatic castration-resistant prostate cancer (nmCRPC)
- Continued research to explore potential of marketed products, evaluating regorafenib (Stivarga™) and radium-223 dichloride (Xofigo™) in combination with immunotherapies

Posters: 1955P, 1916P, 1289P, 542P, 604TiP, 132P, 633P, 694TiP, 631P, LBA68, 990P, 465P, 1010P, 1009P, 829P, 1918P, 1420TiP, 637P, 639P

Berlin, September 8, 2020 – Data from Bayer’s evolving oncology portfolio will be presented at the ESMO Virtual Congress 2020, taking place on September 19-21, 2020. Presentations will highlight differentiated therapies from Bayer that improve patient outcomes, as well as explore efficacy and safety of treatments in different tumor types and in combination with immunotherapies. Information on the registration as well as the virtual scientific program can be found [here](#).

Updated efficacy and safety results with longer follow-up for larotrectinib (Vitrakvi™) from an integrated data set of adult and pediatric patients with tropomyosin receptor kinase (TRK) fusion cancer, as well as new efficacy and safety analyses in patients with lung and thyroid cancers harboring neurotrophic receptor tyrosine kinase (*NTRK*) gene fusions will be presented. Vitrakvi is approved in many markets around the world, including the U.S., Canada, Brazil and the European Union (EU). While local labels might differ, the product

indication spans across patients of all ages with any solid tumors that harbor an *NTRK* gene fusion. Additional filings in other regions are underway or planned.

New findings from the Phase III ARAMIS trial highlighting the continued efficacy and safety profile of darolutamide (Nubeqa™) in patients with non-metastatic castration-resistant prostate cancer (nmCRPC) will be presented. Furthermore, information on a Phase III trial in progress evaluating the addition of darolutamide to androgen deprivation therapy and definitive or salvage radiation in men with localized high-risk prostate cancer will also be shared at this congress. Nubeqa is an oral androgen receptor inhibitor (ARi) developed jointly by Bayer and Orion Corporation, a globally operating Finnish pharmaceutical company. The product is currently approved for the treatment of men with nmCRPC in several markets around the world including the EU, the U.S., Brazil, Canada, and Japan.

Additional research on Bayer's established products in combination with immunology (IO) approaches, including regorafenib and radium-223 dichloride, for first line treatment of advanced hepatocellular carcinoma (HCC) and non-small cell lung cancer (NSCLC) respectively, will also be presented at the meeting.

Notable presentations at the ESMO Virtual Congress 2020 are listed below. Abstracts accepted as posters (P) or Trial in Progress (TiP) will be available online September 14, 2020 at 00:05 CEST and full presentations will be available online from September 17-21, 2020. More information on the registration can be found [here](#).

Larotrectinib

- *Survival benefits of larotrectinib in an integrated dataset of patients with TRK fusion cancer*
 - Session: Translational Research (Agnostic)
 - Poster: 1955P
- *Larotrectinib treatment of advanced TRK fusion thyroid cancer*
 - Session: Thyroid Cancer
 - Poster: 1916P
- *Efficacy and safety of larotrectinib in patients with tropomyosin receptor kinase (TRK) fusion lung cancer*
 - Session: NSCLC, Metastatic
 - Poster: 1289P

- *Growth modulation index (GMI) of larotrectinib versus prior systemic treatments for TRK fusion cancer patients*
 - Session: Developmental Therapeutics
 - Poster: 542P
- *ON-TRK: a non-interventional study of larotrectinib in patients with TRK fusion cancer – **Trial in Progress***
 - Session: Developmental Therapeutics
 - Poster: 604TiP
- *TRKing PTC patients: NTRK gene fusion frequency and clinical characteristics of a Finnish papillary thyroid cancer cohort*
 - Session: Biomarkers (Agnostic)
 - Poster: 132P

Darolutamide

- *Tolerability and treatment response to darolutamide (DARO) in patients with non-metastatic castration-resistant prostate cancer (nmCRPC) in the phase 3 ARAMIS trial*
 - Session: Genitourinary Tumours, Prostate
 - Poster: 633P
- *DASL-HiCaP: Darolutamide Augments Standard Therapy for Localised Very High-Risk Cancer of the Prostate (ANZUP1801). A randomised phase 3 double-blind, placebo-controlled trial of adding darolutamide to androgen deprivation therapy and definitive or salvage radiation – **Trial in Progress***
 - Session: Genitourinary Tumours, Prostate
 - Poster: 694TiP
- *Darolutamide (D), enzalutamide (E) and apalutamide (A), the risk of adverse events (Aes) in patients with non-metastatic castration-resistant prostate cancer (nmCRPC): Number Needed to Harm (NNH)*
 - Session: Genitourinary Tumours, Prostate
 - Poster: 631P

Regorafenib

- *Results of the randomized, placebo (PL)-controlled phase II study evaluating the efficacy and safety of regorafenib (REG) in patients (pts) with metastatic relapsed Ewing sarcoma (ES), on behalf of the French Sarcoma Group (FSG) and Unicancer – **Investigator-Initiated Research (IIR)***

- Session: Proffered Paper – Sarcoma Session, September 20, 17:04 – 17:16
CEST, Channel 1
 - Late-Breaking Abstract: LBA68
- *Updated results of a phase 1b study of **regorafenib (REG)** plus pembrolizumab (PEMBRO) for first-line treatment of advanced hepatocellular carcinoma (HCC)*
 - Session: Hepatocellular Carcinoma
 - Poster: 990P
- *Single nucleotide polymorphism (SNP) analysis identifies potential prognostic and predictive biomarker in patients (pts) with metastatic colorectal cancer (mCRC) treated with regorafenib in the phase III CORRECT trial*
 - Session: Colorectal Cancer
 - Poster: 465P
- *Real-world dosing of regorafenib (REG) in patients (pts) with unresectable hepatocellular carcinoma (uHCC): Interim analysis (IA) of the observational REFINE study*
 - Session: Hepatocellular Carcinoma
 - Poster: 1010P
- *Regorafenib in patients (pts) with unresectable hepatocellular carcinoma (uHCC) in real-world practice in Asia: Interim results from the observational REFINE study*
 - Session: Hepatocellular Carcinoma
 - Poster: 1009P
- *Regorafenib (R) or Tamoxifen (T) for platinum-sensitive recurrent ovarian cancer (PSROC) with rising CA125 and no evidence of clinical or radiological disease progression: a GINECO randomized phase II trial*
 - Session: Gynaecological Cancers
 - Poster: 829P

Sorafenib

- *Final analysis of RIFTOS MKI, a global, non-interventional study assessing the use of multikinase inhibitors (MKIs) for the treatment of patients with asymptomatic radioactive iodine-refractory differentiated thyroid cancer (RAI-R DTC)*
 - Session: Thyroid Cancer
 - Poster: 1918P

Radium-223 dichloride (Ra-223)

- *A phase 1/2 trial of radium-223 (Ra-223) in combination with pembrolizumab in patients (pts) with stage IV non-small cell lung cancer (NSCLC) – **Trial in Progress***
 - Session: NSCLC, Metastatic
 - Poster: 1420TiP
- *The prognostic value of the baseline neutrophil-to-lymphocyte ratio (NLR) in patients with metastatic castration-resistant prostate cancer (mCRPC) receiving radium-223 (Ra-223): a post-hoc analysis of the ALSYMPCA Phase-III trial – **Investigator-Initiated Research (IIR)***
 - Session: Genitourinary Tumours, Prostate
 - Poster: 637P
- *223Ra in asymptomatic patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) who progressed to 1st line abiraterone acetate or enzalutamide – **Investigator-Initiated Research (IIR)***
 - Session: Genitourinary Tumours, Prostate
 - Poster: 639P

About Oncology at Bayer

Bayer is committed to delivering science for a better life by advancing a portfolio of innovative treatments. The company has the passion and determination to develop innovative medicines that help improve and extend the lives of people living with cancer. The oncology franchise at Bayer includes six marketed products across various indications and several compounds in different stages of clinical development. Bayer focuses its research activities on first-in-class innovations across the following scientific platforms: Oncogenic Signaling, Targeted Alpha Therapies, and Immuno-Oncology. Across the areas of focus, we have several prostate cancer treatments on the market or in development, with the goal of extending survival while limiting side effects of treatment throughout the different stages of the disease. Another key focus at Bayer is on innovative precision oncology treatments, with an approved TRK inhibitor exclusively designed to treat tumors that have an *NTRK* gene fusion, the oncogenic driver of tumor growth and spread, and another TRK inhibitor advancing through the pipeline. The company's approach to research prioritizes targets and pathways with the potential to impact the way that cancer is treated.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to benefit people by supporting efforts to overcome the major challenges presented by a growing and aging global population. At the same time, the Group aims to increase its earning power and create value through innovation and growth. Bayer is committed to the principles of sustainable development, and the Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2019, the Group employed around 104,000 people and had sales of 43.5 billion euros. Capital expenditures amounted to 2.9 billion euros, R&D expenses to 5.3 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements

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